Exhibit B-1

Deposition of:

Mark Eisenberg , M.D.

July 6, 2017

In the Matter of:

In Re: Bard IVC Filters Products Liability

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are knowledgeable about the risks and benefits associated with the procedure and the device. That's dependent on having that information available to them.

Q. Let me hand you what we will mark as Exhibit 8.

Exhibit 8 was marked for identification.

BY MR. BUSMAN:

Q. Do you recognize this as the document identified in paragraph 24?

A. Yes.

Q. Take a look at the very top, if you will, right under the heading: "Chapter Two, Opinions on Consent, Communications and Decision Making". I will read it into the record.

"The opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law."

Did I read that correctly?

A. Yes.

Q. Do you agree with that statement?

Q. Let's take a look, please, at paragraph 26. If you could read that to yourself and let me know when you are finished.

A. Okay.

Q. Let me hand you what we will mark as Exhibit 9.

Exhibit 9 was marked for identification.

BY MR. BUSMAN:

Q. Can you identify Exhibit 9 for the record, please?

A. This is titled: "The ACR-SIR-SPR Practice Parameter on Informed Consent For Image Guided Procedures."

Q. Is the document we have identified as Exhibit 9 the document that you refer to in paragraph 26 of your report?

A. The paragraph in my report -- the paragraphs in my report are sub-sections from this document.

Q. Now, Exhibit 9 is a document put out by the American College of Radiology; right?

A. Yes.

Q. In connection with what other groups?

A. With the Society of Interventional Radiology and the SPR.

Q. Do you know what SPR stands for?

A. I think the acronym escapes me for the moment.

Q. Now, are you a member of the American College of Radiology?

A. No, I am not.

Q. Are you eligible to become a member of the American College of Radiology?

A. That I don't know. As I said, I am an interventional cardiologist, so there is some overlap between radiology and interventional cardiology, so it's possible I might be eligible.

Q. Are you a member of the Society of Interventional Cardiology?

A. No, I am not.

Q. There is nothing in paragraph 26 of your report that quotes from these practice guidelines that specifically mentions any obligation, responsibility or duty on behalf of a medical device manufacturer; right?

A. No. As we mentioned earlier, there is no specific mention in these paragraphs of the responsibility of a medical device manufacturer,

although I think there is -- it's implicit in these paragraphs, because these paragraphs discuss how a physician obtains informed consent before doing a procedure, and they have to be able to disclose to the patients the risks, complications and expected benefits of the procedure or device to the patient. So in order to be able to do that they have to know what the risks, complications and benefits are and how frequently they occur.

Q. I am going to object and move to strike as non-responsive. Is there anything in paragraph 26 where you quote from these practice guidelines that specifically references any binding duty, obligation or responsibility of a medical device manufacturer?

MR. ROTMAN: Objection. Asked and answered.

THE WITNESS: No, there is nothing specifically, you know, identifying the responsibility of a medical device company in these paragraphs.

BY MR. BUSMAN:

Q. Is Exhibit 9, in your opinion, the same type of document as Exhibit 8 in terms of

providing ethical guidance to practitioners?

A. Yes, very similar.

Q. Now, if you take a look at Exhibit 9, I am going to read part of it into the record. If you take a look at the preamble on the first page. Do you see that heading?

A. Yes.

Q. "This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients."

Did I read that correctly?

A. Yes.

Q. Do you agree?

A. Yes.

Q. The next sentence states:

"Practice parameters and technical standards are not inflexible rules or requirements of practice and are not intended nor should they be used to establish a legal standard of care."

Did I read that correctly?

are provided by these organizations to provide guidance to physicians on how to obtain informed consent. At the same time, they don't want to expose the physicians to lawsuits if they, you know, if they haven't enumerated every single risk or every single benefit. So they don't want to -- they don't want to set this up as a way for, I think, patients to sue physicians.

Q. Would I be correct that, in your opinion, the documents cited in paragraphs 24, 25 and 26 do not constitute any legally binding obligations for Bard?

MR. ROTMAN: Objection.

THE WITNESS: I think that they -- first of all, it doesn't appear that they are legally binding obligations for physicians, if I understand these sentences correctly. And none of these paragraphs specifically mention medical device manufacturers. So technically I think you are correct. On the other hand, these are, you know, very strongly advised and they are widely accepted amongst physicians that these are the -- these are the components of full and informed consent. If you want to get full and informed consent you have to be fully apprised of the

MR. ROTMAN: Objection.

THE WITNESS: Well, if we could turn to the second part of paragraph 33 where we are talking about it was misleading and detrimental to patient health, safety, and informed consent to continue to sell the earlier devices after the newer ones had been cleared for marketing, so that refers specifically to informed consent. So we have earlier in my expert report a couple of documents that speak to informed consent where the physician has to give the risks and benefits of the procedure or device.

BY MR. BUSMAN:

Q. You are talking about the documents in paragraphs 24, 25 and 26; correct?

A. That's correct.

Q. Is it your opinion that the documents in paragraphs 24, 25 and 26 are in some way, shape or form actually binding on Bard, controlling of its conduct?

A. No. As we discussed earlier, these are strong ethical guidelines for physicians on how to provide informed consent.

Q. So let me try the question one more time. What binding document of any kind, whether

it be a law, rule, standard or regulation, did Bard violate in connection with the conduct outlined in paragraph 33?

A. So again, I can't point you to a particular document. I would say that I have read the expert report of Dr. Kessler who is an FDA expert, and he indicated in his documents that Bard had violated, you know, various FDA rules. I can't point to the particular paragraphs where he said that.

Q. I am going to object and move to strike everything other than "I can't point you to a document." I didn't ask you about Dr. Kessler; okay, or his litigation report in this case. I am going to take your report as a whole for the purpose of my next question; okay? I am referring to your expert report that we have identified here and any rebuttal report or supplemental report that you have served in this case. You have not identified any binding document of any kind, whether it be a law, rule, regulation or guidance that you believe Bard violated in connection with any of your expert opinions in this case; right?

A. Again, I don't know if this gets to